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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/822,186	03/20/1997	DAVID C RUEGER	CRP-137	6062

7590 03/04/2004
JAMES F. HALEY
FISH & NEAVE
1251 AVENUE OF THE AMERICAS
NEW YORK, NY 100201104

EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/822,186

Applicant(s)

RUEGER ET AL.

Examiner

David S Romeo

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,9,11-25,31-33,35 and 36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,9,11-25,31-33,35 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-6,8,9,11-25,31-33,35 and 36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 11/03/2003 has been entered. Claims 1-6, 8, 9, 11-25, 31-33, 35, and 36 are pending. Applicants elected with traverse group III, claims drawn to an osteogenic device comprising an osteogenic protein, cellulose, and a matrix, in Paper No. 45. Applicants elected the species "single osteogenic species OP-1," "single matrix species collagen," and "single cellulose species carboxymethylcellulose" in Paper No. 45. Claims 1-6, 8, 9, 11-16, 20-24, 32, 33, 35, 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), to the extent that they are drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 44. Claims 6, 9, 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species.

Claim Rejections - 35 USC § 103

Claims 1-5, 7, 8, 11-13, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amman (a46) and Ron (AK, cited by Applicants).

The examiner also relies upon Bulletin VC-453C.

Applicants argue that TGF- β is not encompassed by Applicant's defined genus of osteogenic proteins. Applicant's arguments have been fully considered but they are not persuasive. TGF- β is clearly an osteogenic protein, as evidenced by Ammann. Although the specification intends the term "osteogenic proteins" to include members of the family of bone morphogenetic proteins (BMPs) (page 1, lines 10-13), the specification in no way limits the "osteogenic protein" of the present claims to a BMP subgroup of the TGF- β

Art Unit: 1647

superfamily of growth factors. Furthermore, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Furthermore, the claims only require the osteogenic protein be capable of inducing repair of endochondral bone.

5 Applicants argue that Ron does not teach or suggest a binding agent having a viscosity of about 10-200 cP and a degree of substitution of 0.65-0.90. Applicant's arguments have been fully considered but they are not persuasive. Figure 4 of Bulletin VC-453C indicates that even high viscosity grades of CMC having a 0.7 degree of substitution have a viscosity within the range of about 10-200 cP at the appropriate
10 concentration. Accordingly, Ron teaches a binding agent having a viscosity of about 10-200 cP and a degree of substitution of 0.65-0.90.

 Claims 1, 15, 16, 32, 33, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amman (a46) and Ron (AK, cited by Applicants) as applied to claim 1
15 above and further in view of Arnaud (v8) and Turco (w8).

 Applicants argue that TGF- β is not encompassed by Applicant's defined genus of osteogenic proteins. Applicant's arguments have been fully considered but they are not persuasive. TGF- β is clearly an osteogenic protein, as evidenced by Ammann. Although the specification intends the term "osteogenic proteins" to include members of the family
20 of bone morphogenetic proteins (BMPs) (page 1, lines 10-13), the specification in no way limits the "osteogenic protein" of the present claims to a BMP subgroup of the TGF- β superfamily of growth factors. Furthermore, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Art Unit: 1647

Furthermore, the claims only require the osteogenic protein be capable of inducing repair of endochondral bone.

Applicants argue that Ron does not teach or suggest a binding agent having a viscosity of about 10-200 cP and a degree of substitution of 0.65-0.90. Applicant's arguments have been fully considered but they are not persuasive. Figure 4 of Bulletin VC-453C indicates that even high viscosity grades of CMC having a 0.7 degree of substitution have a viscosity within the range of about 10-200 cP at the appropriate concentration. Accordingly, Ron teaches a binding agent having a viscosity of about 10-200 cP and a degree of substitution of 0.65-0.90.

10

Claim Rejections - 35 USC § 112

Claims 1, 8, 9, 11-16, 20-22, 32, 33, 35, 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that the present specification provides ample written description for "osteogenic protein."

The description of an "osteogenic protein" as generally being understood to mean a protein which can induce the full cascade of morphogenic events culminating in endochondral bone formation (page 22, lines 10-12), at best only describes what an "osteogenic protein" does, rather than of what it is. Such a description usually does not satisfy the written description requirement. The written description requirement must be

Art Unit: 1647

met in some way so as to describe the claimed invention so that one skilled in the art can recognize what is claimed. In the present case, relying upon the term "osteogenic protein" does not describe the claimed invention so that one skilled in the art can recognize what is claimed because the term fails to distinguish any "osteogenic protein" from others having the same activity or function. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Thus, generalized language such as "osteogenic protein" does not suffice because it does not convey the detailed identity of the invention.

The features (page 2, lines 6-10 and lines 10-12) and examples (page 23, line 20, through page 25, line 25; page 30, line 7, to page 43, line 13) upon which Applicants rely typify some features of members of a BMP subgroup of the TGF- β superfamily of growth factors. However, although the specification intends the term "osteogenic proteins" to include members of the family of bone morphogenetic proteins (BMPs) (page 1, lines 10-13), the specification in no way limits the "osteogenic protein" of the present claims to a BMP subgroup of the TGF- β superfamily of growth factors. If Applicants intend the "osteogenic protein" of the present claims to only encompass a BMP subgroup of the TGF- β superfamily of growth factors, then Applicants should have no hesitation in importing the structural and functional limitations that define or describe a BMP subgroup of the TGF- β superfamily of growth factors into the present claims.

20

Claims 1-6, 8, 9, 11-25, 31-33, 35, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-6,

Art Unit: 1647

8, 9, 11-25, 31-33, 35, and 36 are indefinite over the recitation of "viscosity of about 10-200 cP" because viscosity of cellulosic materials depends upon the concentration.

Applicants argue that the skilled artisan would readily be able to determine viscosity, that there are numerous factors that affect viscosity and that it is not necessary to recite all the factors that affect viscosity. Applicant's arguments have been fully considered but they are not persuasive. The specification indicates that the degree of substitution and the standard viscosity of an aqueous solution of stated concentration is indicated on any carboxymethylcellulose sodium labeling. However, the claims are not limited to a standard viscosity. The specification also indicates that CMC is available in several grades--low, medium and high viscosity. In this regard, the viscosity of the carboxymethylcellulose (CMC) used to formulate an improved osteogenic device was determined to be critical for bone formation. However, the specification does not indicate the concentration at which the viscosity was determined. The record establishes that, in this case, the term "viscosity" needs to be defined. There is no definition in the specification. Hence, the skilled artisan is left to figure out what "viscosity" would mean in the context of the claimed invention.

New Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32, 33, 35, 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Gomez (A). The claims are directed to or encompass a kit comprising receptacles. The claims do not require that the receptacles contain anything in particular. The claims only
5 require that the receptacles are adapted to house the recited contents. Gomez discloses a kit comprising three receptacles (column 3, full paragraph 2). The receptacles in Gomez's kit are adapted to house the components recited in the present claims in the absence of evidence to the contrary.

10

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37
15 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the
20 shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1647

5 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (571) 272-0887.

10 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

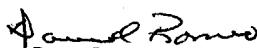
BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

15 CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

20 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.


DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
MARCH 2, 2004